OCT - 1 2003

510(K) SUMMARY

K032723

Prepared on July 22, 2003

Submitter: Getinge USA, Inc.
1777 East Henrietta Road
Rochester, NY 14623

Contact Person: Karla Byrne, Operations Director Consumable Products Division
Telephone: (585) 272-5007 Fax: (585) 272-5271

Common Name: Self-contained Biological Indicator
Propietary Name: Biosign Steam-24 Biological Indicator

Classification: Indicator, Biological Sterilization Process – Class II, 80 FRC

Predicate Device: Biosign Biological Indicator (K872867)

Device Description:

The Getinge Biosign Steam-24 Biological Indicator is a self-contained biological indicator designed for biological testing of steam 121°C and 134°C pre-vacuum and gravity and flash steam sterilization cycles. When used to monitor steam cycles, the product is intended to give the user results after 24 hours incubation. The Biosign Steam-24 Biological Indicator contains 10^4 Geobacillus stearothermophilus (nee Bacillus stearothermophilus) spores/carrier. The Biological Indicator is self-contained with an ampule containing culture medium in the same vial as the spore strip.

The shelflife of the new Biosign Steam-24 Biological Indicator is the same as the unmodified Biosign Biological Indicator (18 months).

The Getinge Biosign Steam-24 Biological Indicator is the same size as, utilizes the same materials and manufacturing processes as the Biosign Biological Indicator. The Biosign Steam-24 Biological Indicator does not contain Bacillus atrophaeus (nee B. subtilis var. niger) and therefor is NOT labeled for use in monitoring ethylene oxide sterilization cycles.

There are no technological differences between the Biosign Steam-24 Biological Indicator and the unmodified device. The same steam indicator spores are utilized, the same media ampule is used, the same packaging materials are utilized and the same manufacturing processes have been utilized.

Intended Use:

The Getinge Biosign Steam-24 Biological Indicator is a steam sterilization monitor designed specifically for biological testing of 121°C, 134°C gravity and pre-vacuum and flash steam sterilization cycles with results available after 24 hours incubation.

Comparison to Unmodified Device:

The Getinge Biosign Steam-24 Biological Indicator's manufacturing material, manufacturing methods and storage conditions are the same as the unmodified Biosign Biological Indicator. The new modified design allows for greater than 97% assurance for 24 hour incubation time per CDRH Guidelines. The Biosign Steam-24 design does not include B. atrophaeus spore for monitoring ethylene oxide and therefor is only labeled for monitoring steam cycles.

ifferent lots of Biosign Steam-24 were tested according to the CDRH
ncubation Time. Results provided greater than 97% assurance for 24
ested per CDRH Guidelines.

Biosign Steam-24 were tested according to the unmodified Biosign
s. All steam resistance criteria were met including Survival / Kill and D-
34°C. The Biosign Steam-24 Biological Indicator is not labeled for use
ses other than steam.

l Indicator is equivalent to the unmodified Biosign BI for monitoring
e improvement of results available after 24 hours incubation.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Ms. Karla Byrne
Consumable Products Operations Director
Getinge USA, Incorporated
1777 East Henrietta Road
Rochester, New York 14623-3133

Re: K032723
Trade/Device Name: Biosign Steam-24 Biological Indicator
Regulation Number: 880.2800
Regulation Name: Sterilization Process Indicator
Regulatory Class: II
Product Code: FRC
Dated: July 23, 2003
Received: September 3, 2003

Dear Ms. Byrne:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4618. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Susan Runner

Susan Runner, DDS, MA
Interim Director
Division of Anesthesiology, General Hospital
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Getinge USA, Inc.
Biosign Steam-24 Biological Indicator

Indications for Use

510(k) Number: K032723

Device Name: Biosign Steam-24 Biological Indicator

Indications For Use:
The Getinge Biosign Steam-24 Biological Indicator is a steam sterilization monitor designed specifically for biological testing of 121°C, 134°C gravity and pre-vacuum and flash gravity and pre-vacuum steam sterilization cycles with results available after 24 hours incubation.

Olivia S. Lin

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices
510(k) Number: K032723

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)